PATENT

S/N 10/672,297

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	WOOD et al.	Examiner:	OLGA ASINOVSKY
Serial No.:	10/672,297	Group Art Unit:	1711
Filed:	09/25/2003	Docket No.:	11816.56USU1
Confirmation No.:	4458		
Title:	GRAFTED CYCLODEXTRIN		

DECLARATION OF MARK HARRISON

I, Mark Harrison, Ph.D., Business Development Manager for Wacker Chemicals Corporation of Adrian, Michigan, depose and say as follows:

1. I received my Ph.D. degree from Heriot-Watt University, Edinburgh, Scotland in 1988.

2. I have been employed in the field(s) of organic intermediates, aroma chemicals and cyclodextrins by Wacker-Chemie from 1988 to 1997, and in 1997 was appointed Business Development Manager for Wacker Chemical Corp., Adrian, Michigan with global responsibility for development, sales and marketing for all industrial applications of cyclodextrins. I have had some 14 years of experience in the field of cyclodextrin applications. I have worked with Mr. Willard E. Wood for many years in the technology related to the invention. I am familiar with the cyclodextrin technology as shown in the Wood et al prior art and the invention

3. I have read comments by the Examiner in the above-captioned U.S. patent application relating to the rejection of the claims over the previous Wood et al. patents. I understand the Examiner to argue that a simple and direct substitution in the invention of a cyclodextrin grafted polyolefin for a small molecule substituted cyclodextrin, such as a

cyclodextrin acetate or a cyclodextrin methyl ether compound, is the substitution of one known and readily available compound for another.

4. Typically, cyclodextrin is used in applications using the water-soluble nature of the material. Most derivatives or small molecular weight cyclodextrin derivatives are highly water soluble and used for solubilisation of hydrophobic groups, stabilization in the dry state, controlled release and modification of odor or taste. The derivative is usually; hydroxypropyl, methyl or other alkylated groups, acetyl or other acyl groups, aromatics, etc.

5. Less water soluble cyclodextrin materials are quite diffcrent. Grafting cyclodextrin onto a polymer is fundamentally different from derivatizing the cyclodextrin with a normal organic moiety. The factual basis for this difference includes the following:

a. Small molecular weight cyclodextrin derivatives typically have molecular substitution (number of derivatives per cyclodextrin) of 3 to 15 derivatizing groups. Cyclodextrins grafted onto polyolefin will have molecular substitution = 1.

b. Typical molecular weight of normal cyclodextrin derivatives is about 973 – 5000 depending on cyclodextrin. Typical polymer molecular weight is 100,000 or more. Molecular weight of the derivatising agent for small molecular weight cyclodextrin derivatives is 50 to 150, for graftable polyolefins the molecular weight is about 20,000 to greater than 100,000. Molecular weight percent of derivatising agent for small molecular weight cyclodextrin derivatives is 10% to 20%, for the grafted polymer it is 95% to 99%.

c. Cyclodextrins with many peripheral -OH groups are hydrophillic and inherently incompatable with polyolefins, which are hydrophobic. Derivatising cyclodextrins with organic functional groups will make cyclodextrins more compatable with the polyolefin matrix. The higher the degree of substitution with organic groups the more compatible the material will be with polyolefins.

d. Small molecular weight cyclodextrin derivatives are produced in the liquid phase using a solvent, e.g. methylation or hydroxypropylation uses the water as the solvent; acetylation uses acetic acid/anhydride as a solvent. The grafting process uses an extruder, no solvent.

e. Typically the main reason for derivatizing cyclodextrins is to improve water solubility, so that cyclodextrins can be used to solubilise low molecular weight hydrophobic

compounds like drug actives. Note cyclodextrin derivatives with a reactive group have been prepared and they have been used to fix the cyclodextrin onto hydrophilic substrates like cotton, cellulose, etc. or to make cyclodextrin polymers.

6. The Examiner's statement that a blend of a small substituent derivatized modified compatible cyclodextrin with polyolefin is a "modified polyolefin: is not correct in this technology. The cyclodextrin is not modified unless the cyclodextrin in covalently bonded to the molecule. Unless the "derivatized modified compatible cyclodextrin" is grafted to the polyolefin it will potentially leach out losing the ability to function as required. A cyclodextrin grafted onto the polyolefin backbone will not leach out.

7. Based on the differences summarized above, the simple small molecule substituent substituted cyclodextrin is such a completely different chemical entity from a cyclodextrin grafted polyolefin that one of ordinary skill in the art would not readily substitute the cyclodextrin grafted polyolefin for a small molecule substituted cyclodextrin in this polymer packaging technology.

8. Prior to the introduction by Mr. Willard E. Wood of polymer compatible cyclodextrins, cyclodextrins were almost always used in aqueous environment. Mr. Wood is the first to attempt to make cyclodextrins compatible with polymer materials.

9. The Wood et al. reference cited by the Examiner is an initial step in attempting to make cyclodextrins compatible in a polymer material. While small molecules substituted cyclodextrins have some compatibility with polymers and can act to prevent the transmission of volatile materials from polymer layers, improvements are required.

10. For that reason, attention was directed to developing a different technology, i.e., grafting cyclodextrins on to a polymer backbone. The grafted polymers are then adapted for blending into bulk polymer layers.

11. In conclusion, recognizing that small substituent derivatives of cyclodextrin such as acetyl cyclodextrin, alkyl ether cyclodextrin and hydroxyl alkyl ether cyclodextrin can be manufactured, one of ordinary skill in the art could not readily adapt this technology to polymer grafted cyclodextrins. The materials are substantially different in the manner discussed above.

12. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such false statements may jeopardize the validity of the application or any patent issued thereon.

11/11/2005
Date

Mark Harrison